

**WTO-WHO Workshop on Differential Pricing and Financing of Essential
Pharmaceuticals: 8 – 11 April 2001
Hosbjo, Norway**

**10:30-12:30 – Session I - Access to Essential Drugs in Low Income Countries:
Key Issues - ROLE OF GOVERNMENT IN HEALTH CARE**

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This outline is in three parts. *The first part* outlines the general scope of role of Government in the context health care of low income countries; *the second part* outlines approaches and options being applied by Government to ensure access to essential drugs; and, *the third part* examines possible actions for long term actions to ensure access to essential drugs on a sustainable basis through capacity building for technology diffusion into low income countries.

1. General Scope of the Role:

This outline on the role of Government focuses on the context of this role with respect to the access of essential drugs in the developing low income countries. There is much written on the subject but the primary role of Government in health care remains that of giving leadership in the promotion of health through actions against key health problems, that are generally articulated in National Health Policies aiming at:

- 1.1 Implementing reforms of **Regulations** to ensure *social justice, ethics* and access to health care in general and to essential drugs in particular; This is a very fundamental action to ensure that the necessary infrastructure is in place to support service delivery. Access to health care services is often available to less than 50% of the population and less than 35% of pregnant women have access to facilities for assisted delivery. The consequence is that mortality rate are un-acceptably high for a time of technologic advancement, such as that of today.
- 1.2 Implementation of Reforms of **Standards** for improving *protection* of the of people by laying down minimum requirements for facilities and equipment; human resources, drugs and other medical supplies; as well as for operating systems and procedures. The distribution of facilities is heavily in favour of a few urban populations and the yet these facilities are not only in a state of disrepair but operate at very low capacity for lack of supplies and trained human resources.
- 1.3 Implementing Reforms of the health care management systems so as to facilitate Monitoring for ensuring **equity** of access and of outcomes; At present, health management information systems and operation manuals

are poorly developed to guide management policy decisions for planning and re-planning of services.

1.4 **Reforming the health care programmes** for delivery of services to focus upon *cost effective approaches against the leading causes of the high burden of ill-health*. The current balance of curative to preventive and health promotion programmes requires action to gain more efficiency. The priority is to focus upon those programmes with a higher value of public good and, to promote programmes that facilitate community participation in **public health affairs and information dissemination through better democratic governance**.

1.5 Implementation of reforms of the **health care financing mechanisms** toward **risk-sharing payment systems** as well as **increased health care budgets**, in general and, **for drugs and personnel, in particular**.

1.6 Implementation of programmes for **capacity building through technology diffusion** by collaboration between Public sector – Private sector- International community (through bilateral linkages) and, - Multilateral Technical Agencies (such as WHO etc). This is the most fundamental action to ensure long-term sustainability of effective programmes for attainment of poverty reduction and better health of people in the developing countries.

2. Government Action for Essential Drug Policies

- 2.1 In general, Governments in the developing countries (as else where), are significantly involved in the pharmaceuticals industry for a variety of reasons to ensure protection of social values and promote public goods.
- Governments act from a social and cultural context to regulate the market dynamics of drugs as unique products for “life and death”;
 - Government action has been necessary to effect “essential drugs legislations” for ensuring the availability of “good quality”, “potent” yet “safe” and “cost-effective” (value for money) drugs, under the constrained budgets and low level of technologic development (poor skills and facilities/equipment) of low income countries;
 - Patent protection creates monopolies requiring action by Governments to avoid over-pricing in an environment of information asymmetry; The pharmaceutical industry has unique supply and (three tier) demand structural features. The supply side being highly regulated for safety, quality and efficacy (is capital intensive) while, the demand side comprises end user with little control on choice because of it's three tiers of prescribers (physicians), who chose

the drugs; the distributors (pharmacists), who dispense the drugs, and, finally the consumers (patients/clients) who use the drugs.

2.2 The **Supply side government interventions** to avail essential drugs target:

- Producers; this is very limited in the context of low income countries because there are very few manufacturers;
- The number of products licensed and by restrictions on the number of drugs in the essential drugs formulary (*The practice of Rational Selection*);

2.3 The **Demand side government interventions** to avail essential drugs target:

- Agents acting on behalf of patients – (these represent a proxy-demand and comprise prescribing physicians and dispensing pharmacists etc) - like through budgets ceilings, and prescribing guidelines (*The practice of Rational Use of Drugs*)
- “End” Consumers through co-payments; cost recovery schemes (the Bamako initiative drug revolving funds and cost-sharing through user-fee policies. The latter have been particularly difficult to apply consistently all the time. Recent abolition in Uganda has resulted in a very big rise of utilization of public facilities. Trend observation and monitoring are necessary before firm conclusions are drawn.

2.4 **Direct Price regulation:**

- This is the most contentious issue or instrument:
- A large range of approaches exists (from free pricing, through reference pricing; cost-plus pricing / differential pricing and direct price control)
- In general however, global price policies need to operate simultaneously on the supply and demand side;
- It also recognized that price interventions may pose the risk of damaging both the ability of industries to recover R & D investment costs, thus subsequently damaging willingness to continue with innovations;
- However, there is increasing evidence that carefully negotiated price concessions could result in minimum of distortions;

- It is also noteworthy that some flexibility exists in current international conventions / treaties on Intellectual Property Rights for voluntary / *compulsory licensing, advanced generic registration and parallel importation* of protected products but consensus on the application and practice of these provisions is yet to be attained.

3. Government Action to address the technologic-know-how Asymmetry

- 3.1 Many Government actions in the face of **globalizations** have focused upon the macro-economic issues admittedly with some success but, at the expense of some key considerations for technology transfer to developing countries – **the balance of macroeconomic issues and technical micro-issues require re-consideration**; the poor financing of hospitals and operational research were an error that has constrained rather than promoted the implementation of Primary Health Care in low income countries.
- 3.2 Innovations with investments for health care development through sector wide approaches (**SWAps**), **need to be carefully monitored for this short-coming** to ensure technology diffusion and mitigate both poverty and ill-health;
- 3.3 International Technical Agencies in health care (like **WHO**) **need to regain center-stage position in multilateral to developing country Government discussions of policy options for health development**, because of their comparative advantage as a medium for technology diffusion to the low income countries.
- 3.4 Developing Country Governments require to **focus more, toward an agenda facilitated by International Multilateral Agencies, to build bridges** toward participation in the G7/8 forum to better mitigate the political barriers to economic decisions that impede technology transfer to low income countries. At present, negotiations hardly it at all involve them.
- 3.5 The real **challenge to WHO, (Governments, NGOs, Consumers and all people interested in social justice for development, of the collaborations proposed above, is how the TRIPs agreement can be used to ensure access by the poor, to innovation and affordability of pharmaceuticals.**

Author Bibliographic outline:

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